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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,007	11/20/2003	Randolph Mellus Johnson	DURE-007CON2	9101

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,007	JOHNSON ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, response under 37 C.F.R. 1.111, and terminal disclaimer, all filed 12/23/2005.

Claims 48-91 are pending and included in the prosecution.

Terminal Disclaimer

1. The terminal disclaimer filed on 12/23/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of each of US patents: 6,689,373, 6,835,194, and 6,541,021 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following rejections are discussed in the previous office action, and are maintained:

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 48-91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 11/044,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to method for providing analgesia by delivering fentanyl using a convective device that can be implanted (claim 58) and the conflicting claims of the copending application are directed to the same subject matter which is method for treating pain by delivering fentanyl using implanted device. The instantly claimed implantable convective device is a species for the generic implantable device for delivering fentanyl that claimed by copending application. Therefore the instant claims anticipate the generic implantable device claimed by the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

4. Applicants requested that the provisional double patenting rejection to be held in abeyance until the subject rejection is the only one remaining in either the present application or in the 11/044,521 application.

The examiner acknowledges applicants' request, however, the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 48-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,412,139 ('139) in view of US 5,980,927 ('927).

US '139 teaches osmotic device for controlled and continuous delivery of beneficial drug over a prolonged period of time to produce systemic effect (col.1, lines 50-60; col.7, lines 9-10). The device can be implanted (col.4, line 15). Analgesics can be delivered by this device.

US '139 does not teach fentanyl in particular to be delivered by the osmotic device, nor its amount in the device and its delivery rates.

US '927 teaches method for continuous administration of analgesics from implantable device for prolonged period of time up to several months (abstract; col.6, lines 66-67). Fentanyl is the preferred analgesic because of its high potency (col.4, lines 38-43).

The amount and delivery rate of the active agent do not impart patentability to the claims, absent evidence to the contrary. It is within the skilled artisan to manipulate the amount of the active agent to achieve a specific delivery profile according to specific patient need.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the implantable osmotic delivery device disclosed by US '139 that deliver analgesics continuously for prolonged period, and replace the analgesic drug by fentanyl disclosed by US '927, motivated by the teaching of US '927 that fentanyl is a preferred analgesic because of it high potency, with reasonable

expectation of the having implantable osmotic delivery device that continuously deliver fentanyl for prolonged time to relieve pain in patient in need for such treatment.

Response to Arguments

8. Applicant's arguments filed 12/23/2005 have been fully considered but they are not persuasive. Applicants traverse this rejection by arguing that the present claims 48, 63 and 84 require very low volume rate of fentanyl to be delivered, and claim 63 further requires exceptionally high concentration of fentanyl in the device. Higuchi ('139) is related to the invention on the sole basis that it describes an osmotic pump system, and never taught high concentration of fentanyl and low volume of delivery. Nelson ('927) teaches solid implant, and Higuchi's osmotic pump obviously delivers liquid formulation, and one cannot deliver solid formulation in the pump, thus the devices of Higuchi and Nelson are not combinable. Therefore, applicants' claimed method is not obvious over the combination of Higuchi and Nelson.

In response to these arguments, applicants attention is directed to the scope of the claims which is an convective delivery system to deliver fentanyl at low doses for prolonged time, and Higuchi teaches continuous delivery of drug including analgesics in a diluted amount, i.e. low rate, over a prolonged period, as desired by applicants. However, Higuchi does not specifically teach fentanyl as the analgesic to be delivered by the osmotic pump. Nelson is relied upon for the solely teaching of fentanyl as a preferred highly potent analgesic suitable for prolonged delivery periods, and not relied upon for teaching any device or formulation. Therefore one having ordinary skill in the

art would have been motivated to replace the analgesic in the osmotic pump device disclosed by Higuchi with fentanyl because Nelson teaches that fentanyl is the preferred analgesic because of its high potency, with reasonable expectation of having an osmotic pump device that delivers fentanyl in a diluted amounts for prolonged period of time, as desired by applicants. Higuchi and Nelson are analogous art and when combined, will teach the present invention of osmotic pump delivering diluted amount of fentanyl for prolonged period. However, the combination of the references does not specifically teach the same delivery volume or the concentration of fentanyl in the device as claimed by applicant. The delivery volume and concentration of a fentanyl in the osmotic pump is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize according to individual patient condition. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal delivery volume and concentration of fentanyl in order to best achieve the desired results of pain relief. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of fentanyl delivery volume and concentration would have been obvious at the time of applicant's invention.

Response to Arguments

9. Applicant's arguments filed 12/23/2005 in the response under 37 C.F.R.1.111 with respect to the rejection of claims 48-91 under 35 U.S.C. 103(a) as being unpatentable over US 6,287,295 ('295) in view of US 5,980,927 ('927) have been fully

considered and are persuasive. The obviousness rejection of claims 48-91 over '295 over '927 has been withdrawn.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali